K063361

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 2 1 2006

1. Device Name	Magnetic Resonance Diagnostic Device Accessory
Model Name:	MRT 1503/S5, MRT-1503/S3
Trade/Proprietary Name	EXCELART Vantage Atlas-Z, Atlas-X
2. Establishment Registration No.:	2020563
3. U.S Agent Name and Address:	Toshiba America Medical Systems, Inc.
	2441 Michelle Drive
	Tustin, CA 92780
Contact Person:	Paul Biggins
	(714) 730-5000
4. Manufacturing Site:	Toshiba Corporation
	Medical Systems Company
	1385 Shimoishigami
	Otawara-shi, Tochigi 32408550, Japan
5. Date of Submission:	November 1, 2006

6. DEVICE DESCRIPTION

The EXCELART Vantage Atlas is a 1.5 tesla Magnetic Resonance Imaging (MRI) System. The Atlas has a 1.4 m short magnet (55 cm field of view) and includes Toshiba's Pianissimo™ technology (scan noise reduction technology). The wide bore has a 655 mm opening.

There are two models in the EXCELART Vantage Atlas line as follows:

• EXCELART Vantage Atlas-Z	Model No. MRT-1503/S3
• EXCELART Vantage Atlas-X	Model No. MRT-1503/S3

The EXCELART Vantage Atlas MRI System is comparable to the EXCELART Vantage ZGV MRI System (K060003, cleared January 18, 2006) with the following modifications:

- 16 Channel phased array system control
- CPU performance of the computer system has been enhanced
- The longitudinal movement of the patient couch has been increased
- Additional table top coil ports
- Additional RF coils – Atlas SPEEDER Head, Atlas SPEEDER Spine, and Atlas SPEEDER Body)
- SAR limit is 4 W/kg for whole body in conformance with IEC 60601-2-33 (2002)

6.1. Summary Of Major Hardware Changes

a. Maximum supported phased array channel has been increased from 8 to 16.

b. CPU performance of computer system has been enhanced.

c. Patient couch longitudinal movement has been increased.

d. Table top coil ports have been added.

e. Atlas SPEEDER Head and Atlas SPEEDER Spine and Atlas SPEEDER Body are added to the available coil list.

6.2. Summary Of Major Software Changes

a. 16 channel phased array system control.

b. New CPU correspondence.

c. New patient couch control.

d. New RF coil control.

e. SAR limitation control.

7. SAFETY PARAMETERS

	Current EXCELART Vantage™ ZGV (No changes from the previous submission, K060003)	**New EXCELART Vantage Atlas-Z/Atlas-X**
a. Static Field Strength:	1.5 T	Same
b. Peak and A-weighted Acoustic Noise:	110 dB (A-weighted)	Same
c. Operational Modes:	1st operating mode for dB/dt and SAR	Same
i. Safety Parameter Display:	SAR, dB/dt	Same
ii. Operating mode access requirements:	Allows access to 1st level operating mode	Same
d. Maximum SAR	3W/kg for whole body (1st operating mode specified in IEC 60601-2-33 (2002))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33 (2002))
e. Maximum dB/dt and Gradient Coil Dimensions:	<1st operating mode specified in IEC 60601-2-33 (2002) 692 x 893 x 1405 (unit: mm)	Same Same
f. Potential Emergency Conditions and Means Provided for Shutdown:	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects	Same
g. Biocompatibility of Materials:	Not applicable	Same

8. IMAGING PERFORMANCE PARAMETERS

No changes from the previous submission, K060003 .

9. INTENDED USE

No changes from the previous submission, K060003 .

10. EQUIVALENCY INFORMATION

Toshiba Medical Systems Corporation believes that the new EXCELART Vantage Atlas-Z and Atlas-X (model MRT-1503/S5, MRT-1503/S3) Magnetic Resonance Imaging (MRI) system are substantially equivalent to the current EXCELART Vantage™ ZGV (model MRT-1503/P5) (K060003) cleared on January 18, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party
Regulatory Technology Services LLC
1394 26th Street NW
BUFFALO MN 55313

NOV 2 1 2006

Re: K063361
Trade/Device Name: EXCELART Vantage Atlas Model MRT-1503
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 4, 2006
Received: November 7, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number (if known): K063361

Device Name: EXCELART Vantage Atlas-Z, EXCELART Vantage Altas-X

Indications for Use:

Imaging of:

- The Whole Body (including head, abdomen, pelvis, limbs and extremities, spine, neck, TMJ, heart, blood vessels). [Application terms include MRCP (MR Cholangiopancreatography), MR Cisternography, MR Urography, MR Myelography, MR Fluoroscopy, SAS (Surface Anatomy Scan), Dynamic Scan,Cine Imaging and Cardiac tagging.]
- Fluid Visualization
- 2D / 3D Imaging
- MR Angiography / MR Vascular Imaging
- Blood Oxygenation Level Dependent (BOLD) imaging
- Perfusion / Diffusion Imaging
- Proton Spectroscopy

Prescription Use ✓ OR Over-The-Counter Use_____
(Part 21 CFR 801Subpart D) (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063361